K132426

FEB 14 2014

Attachment 9

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Sylphar Remesense Sensitivity Relief Strips
Type of 510(k) submission:	Traditional
Date of Submission:	29 August 2013
Manufacturer:	Sylphar N.V. Xavier de Cocklaan 42 B-9831 Deurle Belgium
FDA Registration Number:	3004847139
510(k) Owner:	Sylphar N.V. Xavier de Cocklaan 42 B-9831 Deurle Belgium
Phone: **Fax:**	+32 (0)9 321 70 80 +32 (0)9 321 70 90
FDA Registration Number:	3006673777
Owner/Operator Number:	10034642
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	LBH
FDA Regulation Number:	872.2360
FDA Classification Name:	Varnish, Cavity
Classification Panel:	Dental
Common Name:	Tooth Desensitizer
FDA Panel:	Dental
FDA Classification:	Class II
FDA Identification:	Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

Indications for Use: Remesense Sensitivity Relief Strips are intended to aid in the relief of dentinal sensitivity resulting from cold, heat, acids, or sweets.

Device Description:

Remesense Sensitivity Relief Strips are polyethylene strips with dimensions of approximately 30 x 10 mm. On the strips is a gel which contains a tooth desensitizing agent, dipotassium oxalate. The directions for use provided with the device instruct the patient to apply one or more strips on the outer gum line of any teeth that are causing sensitivity problems.

The dipotassium oxalate in the gel of the Remesense Sensitivity Relief Strips device forms oxalate crystals which block the open dentinal tubules, thus preventing the stimuli that may cause the sensitivity. By blocking the tubules, the crystals at the tooth surface stop the signals from hot or cold food reaching the dental nerve, providing a remedy for hypersensitivity.

The component parts of the subject device are:

- Outer box with inner plastic sleeve
- Foil pouches (2 or 18 per pack), each containing a single desensitizing strip, mounted on a plastic release backing
- The gel on each strip contains glycerin, aqua, potassium oxalate, carbopol, carboxy-methyl-cellulose (CMC), potassium sorbate, sodium benzoate, sodium hydroxide (NaOH) (50% solution)
- Instruction sheet

Performance Data:

An *in vitro* test utilizing the 'Pashley' model has been conducted to demonstrate that the specific gel formulation used in the Remesense Sensitivity Relief Strips causes oxalate crystals to form in the tubules of teeth. Test results demonstrate no significant difference in flow reduction between the subject device, Remesense Sensitivity Relief Strips, and the predicate device, Remesense for Sensitive Teeth, when applied for 10 minutes, as per the instructions for use of both devices.

In summary, Remesense Sensitivity Relief Strips (subject device), Remesense For Sensitive Teeth (predicate device), and a dipotassium oxalate solution at the same concentration and pH as the Remesense products, all produced highly significant reductions in flow through human dentin after treatment. The occlusions formed from all three oxalate treatments were similar in shape, texture and location. Elemental analysis showed the occlusions formed from the treatment with Remesense Sensitivity Relief Strips are oxalate based.

The same study also assessed the occlusion potential of a Remesense Sensitivity Relief Strip placebo gel control (no dipotassium oxalate) and a water control. Neither the placebo gel nor the water provided any quantitative reduction in flow, and cross sectional analysis of the tested dentin did not show any evidence of occlusions, demonstrating that any occlusion and desensitizing effect is caused only by the oxalate component and not by the gel.

In order to confirm comprehension of the device labelling and the minimization of the potential for use error, a usability study was carried out. The conclusion from the usability study was that patients suffering from tooth hypersensitivity are able to understand the labelling and instructions, and use the device in accordance with the instructions for use provided by the manufacturer.

One new risk of use identified was the risk of choking on the polyethylene strips, especially if a number of strips were used at the same time. In order to assess this risk, a study was carried out by a third party laboratory.

Biocompatibility:

Biocompatibility testing has been carried out in accordance with the recommendations of ISO 10993-1, specifically tests have been conducted in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO

10993-10:2010. The requirements of ISO 7405:2008 have also been considered in establishing the biocompatibility test regime for the device.

Comparison with predicate devices:

The predicate device selected for comparison with the Sylphar Remesense Sensitivity Relief Strips is:

Predicate Device: ..... Sylphar Remesense for Sensitive Teeth
510(k) Sponsor: ..... Sylphar N.V.
510(k) Number: K122708
Clearance Date: ..... 14 January 2013
FDA Product Code: ..... LBH
Classification Name: ..... Varnish, Cavity
Regulation No: 872.3260

This 510(k) submission describes a delivery system for the desensitizing ingredients of the subject device formulation that is different from that used in the predicate, Sylphar Remesense for Sensitive Teeth. Sylphar Remesense for Sensitive Teeth used foam pads impregnated with the desensitizing gel, and the pads were mounted in a mouth-shaped tray, so that the desensitizing agent was applied to a number of teeth at the same time. Remesense Sensitivity Relief Strips uses a gel with a very similar formulation coated on a polyethylene strip, which may be applied directly to only the sensitive areas. Multiple strips are included in the pack, so that a number of sensitive teeth can be treated at the same time if required.

Remesense Sensitivity Relief Strips is intended for over-the-counter (OTC) use, which is the same as for the predicate device.

The subject device and the predicate device use the same mode of action (tubule occlusion) and desensitizing substance (potassium oxalate), and have identical indications for use statements.

The subject device and the predicate device are very similar with the only significant difference being the desensitizing gel delivery system (gel-coated polyethylene strips instead of foam impregnated pads). This difference has no significant effect on safety or effectiveness, as demonstrated by the results of *in vitro* tests on both the subject device and predicate device.

The incidental excipients included in the gel formulation for the subject device are different from those in the predicate device, because the viscosity of the gels used in the subject device and predicate device needs to be different, due to the different methods of delivery. This difference has no significant effect on safety or effectiveness.

Conclusion:

Based on the information contained within this submission, it is concluded that 'Sylphar Remesense Sensitivity Relief Strips' is substantially equivalent to the identified predicate device already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Sylphar N.V.
C/0 Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania 10
Rome, Italy 00153

Re: K132426
Trade/Device Name: Sylphar Remesense Sensitivity Relief Strips
Regulation Number: 21 CFR 872.2360
Regulation Name: Tooth Desensitizer
Regulatory Class: Class II
Product Code: LBH
Dated: January 14, 2014
Received: January 16, 2014

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132426

Device Name: Sylphar Remesense Sensitivity Relief Strips

Indications for Use:

Sylphar Sensitivity Relief Strips are intended to aid in the relief of dentinal sensitivity resulting from cold, heat, acids, or sweets.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	☒

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
Mary S. Runner -S
2014.02.14
12:59:21 -05'00'